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KAREN L ELBING
CLARK & ELBING
176 FEDERAL STREET
BOSTON, MA 02110

EXAMINER	
SWARTZ, RODNEY P	
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Attached is a second Examiner's Answer to Applicants' Brief on Appeal. The first Examiner's Answer appears to have been administratively misplaced within the USPTO prior to the original mailing date of 5/7/01.

RODNEY P SWARTZ, PH.D
PRIMARY EXAMINER

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BEFORE THE BOARD OF PATENT APPEALS

AND INTERFERENCES

Paper No. 23

Application Number: 08/962,750

Filing Date: November 3, 1997

Appellant(s): Frederick M. Ausubel, Laurence G. Rahme, Man-Wah Tan, Gary B. Ruvkun, Shalina Mahajan-Miklos, Annegien Broeks, Ronald H.S. Plasterk, George Jander, Jacqueline Heard, assignee: The General Hospital Corporation, and assignee: The Netherlands Cancer Institute

Karen L. Elbing, Ph.D.

For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 20February2001.

(1) Real Party in Interest

A statement identifying the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

A statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

(3) Status of Claims

The statement of the status of claims contained in the brief is incorrect. A correct statement of the status of the claims is as follows:

Claims 25 and 27 been canceled.

Claims 31-45 are withdrawn from consideration as not directed to the elected invention.

This appeal involves claims 1-24, 26, and 28-30.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Invention

The summary of invention contained in the brief is correct.

(6) Issues

The appellant's statement of the issues in the brief is correct.

(7) Grouping of Claims

The rejection of claims 1-24, 26, and 28-30 stand or fall together because appellant's brief does not include a statement that this grouping of claims does not stand or fall together and reasons in support thereof. See 37 CFR 1.192(c)(7).

(8) Claims Appealed

The copy of the appealed claims contained in the Appendix to the brief is correct.

(9) Prior Art of Record

The following is a listing of the prior art of record relied upon in the rejection of claims under appeal.

Elrod, R.P., et al. "Pseudomonas aeruginosa: its role as a plant pathogen." *Journal of Bacteriology*, 46:633-645, 1942.

Kominos, S.D., et al. "Introduction of Pseudomonas aeruginosa into a hospital via vegetables." *Applied Microbiology*, 24(4):567-570, 1972.

Conrad, D.A., et al. "Efficacy of aztreonam in the treatment of skeletal infections due to Pseudomonas aeruginosa." *Reviews of Infectious Diseases*, 13(Suppl. 7):S634-S639, 1991.

Geels, F.P., et al. "Pseudomonas tolaasii control by kasugamycin in cultivated mushrooms (*Agaricus bisporus*)." *Journal of Applied Bacteriology*, 79:38-42, 1995.

Schroth, M.N., et al. "Epidemiology of Pseudomonas aeruginosa in agricultural areas." *Pseudomonas aeruginosa: Ecological Aspects and patient Colonization*, pages 1-29, 1977.

(10) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claims 1-24, 26, and 28-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Elrod et al (*J. Bacteriol.*, 46:633-645, 1942) or Schroth et al (*Pseudomonas aeruginosa: Ecological Aspects and patient Colonization*, pages 1-29, 1977) in view of Kominos et al (*Appl. Microbiol.*, 24(4):567-570, 1972) and further in view of Geels (*J. Appl. Bacteriol.*, 79:38-42, 1995) and in further in view of Conrad et al (*Rev. Inf. Dis.*, 13, supplement 7:S634-639, 1991).

Elrod et al teach pathogenicity across plant and animal barriers. Specifically, Elrod et al identify a pathogen, *Pseudomonas aeruginosa*, that infects humans(page 633, last paragraph) as well as plants (section *Phytopathogenicity of Pseudomonas aeruginosa*, pages 639-641). It was noted that various strains of this bacterium had lost their pathogenicity for animals, but they had retained the ability of attacking plant tissues

(page 641, paragraph 1). Therefore, Elrod et al teach the use of plant virulence models, as well as animal models for the same pathogen for the study of virulence of a pathogen. In addition, Elrod et al teach that *P. aeruginosa* serves a dual pathogen role, infecting animals and plants, thus teaching that for such dual pathogens, utilizing both animal and plant models is known.

Schroth et al teach the pathogenicity across plant and animal barriers. Specifically, Schroth et al teach that *Pseudomonas aeruginosa* infects patients in hospitals as well as agricultural plants (page 1, first paragraph; Table 1; section **Pathogenicity of P. aeruginosa in Plants**, page 16-22).

Kominos et al teach that vegetables are an important source and vehicle by which *P. aeruginosa* colonizes the intestinal tract of patients (Abstract; section **Isolation of P. aeruginosa from vegetables**, page 567-568; Table 2; Table 3).

Thus, the teachings of Elrod et al, Schroth et al, and Kominos et al indicate that *P. aeruginosa* is a pathogen frequently involved in disease in both plants and animals. Because of this, it would have been obvious at the time the invention was made to a person having ordinary skill in the art to test drug efficacy of a variety of suspected compounds for controlling or eradicating the presence of *Pseudomonas* sp. or *P. aeruginosa* strains in both plants and animals. As such, it also would have been obvious at the time the invention was made to a person having ordinary skill in the art to utilize models of both plants and animals in order to identify those compounds which work best in plants and/or animals.

Conrad et al teach human clinical models to identify a compound (aztreonam) which is efficacious for treatment of a pathogen (*P. aeruginosa*) (Abstract; section **Patients and Methods**, page 634-636).

Geels teaches a plant model to identify a compound (kasugamycin) which is efficacious for treatment of a pathogen (*P. tolaasii*) (Abstract; section **Materials and Methods**, page 38-39).

Thus, the cited references teach that *Pseudomonas* is a pathogen frequently involved in disease in both plants and animals. Because of this, it would have been obvious at the time the invention was made to a person having ordinary skill in the art to test drug efficacy of a variety of suspected compounds for controlling or eradicating the presence of *Pseudomonas* in both plants and animals. In addition, it would have been obvious to utilize models of both plants and animals in order to identify such compounds.

(11) Response to Argument

Appellants argue that none of the cited references in combination teaches or suggests applicants' invention, i.e., using two different eukaryotic organisms together for screening therapeutics that inhibit or reduce pathogenicity of the same pathogen on different hosts.

Appellants argue that Elrod et al teach away from the method claimed. While recognizing that the pathogen *P. aeruginosa* is capable of infecting both humans and plants, Elrod et al concluded that such dual pathogenicity resulted from different virulence factors, not common virulence factors as the instant application teaches, and possible from the existence of different strains of the same bacterium. Therefore, Elrod et al does not reasonably suggest a method utilizing two different hosts to identify therapeutic compounds, and one skilled in the art would not be motivated to employ plants and animal hosts together for screening compounds.

The instant claims are directed to a method of identifying compounds which inhibits or reduces pathogenicity of the same pathogen in at least two different eukaryotic organisms, one of which is a non-rodent. The claims are not directed to identifying common or different virulence factors, but merely state a description of the pathogen as "said same pathogen utilizing a common virulence factor to infect said eukaryotic organisms" and that a compound's inhibition or reduction of pathogenicity is "a consequence of affecting the function of said common virulence factor in said pathogen". Therefore applicants' argument that any cited reference must teach or suggest that the pathogenicity in plants and animals by a single pathogen is due to common or different virulence factors is directed to a criticality not claimed. The claims merely require that the method be performed in at least two different eukaryotic organisms. Elrod et al teach that: 1) "From the results of the biochemical and serological tests it is evident that the two isolates of *P. polycolor* are indistinguishable from certain strains of *P. aeruginosa*."(page 641, first sentence of *Discussion*); 2) "From the above facts it would be impossible to separate *P. polycolor* from *P. aeruginosa*, and we conclude that the two are identical." (Page 641, last sentence to page 642, line 2); and 3) "The ability of *P. aeruginosa* to thrive in plant tissues as well as in warm-blooded animals makes it unique in the field of bacteriology." (Page 643, last sentence of *Summary*). Therefore, Elrod et al teach the same pathogen in plants and animals. This pathogen, *P. aeruginosa*, is the same pathogen utilized in the instantly claimed invention.

Appellants argue that Schroth et al provide no scientific basis for performing appellants' claimed methods even though appellants do not specifically disagree with the Office"s position that Schroth et al do teach that *Pseudomonas aeruginosa* infects patients in hospitals as well as agricultural plants. Appellants' argument is based upon the same argument utilized against Elrod et al, above, that Schroth et al fail to

recognize that dual pathogenicity of *Pseudomonas* results from the existence of common virulence factors and therefore there is no logical suggestion that effective inhibitory compounds for treating or preventing pathogen infection in one eukaryotic organism might be identified by screening in an entirely different eukaryotic organism.

As stated in the examiner's discussion of the Elrod et al arguments, because the claims are not directed to identifying common or different virulence factors, Appellants' argument concerning recognition of whether the pathogenicity in plants and animals is due to common or different virulence factors is directed to a criticality not claimed. Appellants argue that because Schroth et al do not teach that the same strain of *Pseudomonas* is responsible for both infections, one skilled in the art would be led to believe that these infections were caused by different strains, one specific for human patients and the other specific for agricultural plants.

Schroth et al teach that *Pseudomonas aeruginosa* infects patients in hospitals as well as agricultural plants (page 1, first paragraph; Table 1; section **Pathogenicity of P. aeruginosa in Plants**, page 16-22), and does not teach or suggest different strains. Therefore, contrary to applicants' belief, one skilled in the art may very well conclude that these infections were caused by identical organisms.

Appellants argue that Kominos et al even when combined with Elrod et al and Schroth et al does not teach or suggest appellants discovery that a single pathogen possesses common virulence factors that render it pathogenic on multiple host organisms, much less that nematodes and plants may be used together to identify compounds that inhibit or reduce the pathogenicity of a pathogen. Appellants argue that Kominos et al never teaches or suggests that *Pseudomonas* is a pathogen of plants.

Appellants' arguments concerning recognition of whether the pathogenicity in plants and animals is due to common or different virulence factors is directed to a criticality not claimed (see discussion of Elrod et al, above). Kominos et al is utilized only for their teaching that plants are an important source and vehicle by which *P. aeruginosa* colonizes the intestinal tract of patients.

Appellants argue that Conrad et al does not suggest nor provide motivation for any aspect of the claimed invention, but are singularly focused on determining the efficacy of one particular compound to treat *P. aeruginosa* skeletal infections in humans. Moreover, Appellants argue that like all of the other cited references, Conrad et al does not teach or suggest appellants' discovery that a single pathogen possesses common virulence factors that render it pathogenic on multiple host organisms, much less that nematodes and plants may be used together to identify compounds that inhibit or reduce the pathogenicity of a pathogen.

As stated before in the discussions of the other cited references, Appellants' arguments concerning recognition of whether the pathogenicity in plants and animals is due to common or different virulence factors is directed to a criticality not claimed.

In general, in response to Appellants' argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988)and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, the cited references teach that *Pseudomonas* is a pathogen frequently involved in disease in both plants and animals, and that transmission of *Pseudomonas*

to patients in hospitals may be through ingestion of infected agricultural plants. Because of this nexus, it would have been obvious at the time the invention was made to a person having ordinary skill in the art to test drug efficacy of a variety of suspected compounds for controlling or eradicating the presence of *Pseudomonas* in both plants and animals. In addition, it would have been obvious to utilize models of both plants and animals in order to identify such compounds.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

August 27, 2002

Conferees

Rodney P. Swartz, Ph.D., Primary Examiner, AU1645

Lynette Smith, SPE, AU1645

James Housel, SPE, AU1648